

## CLAIMS

What is claimed is:

- Sub 114
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1. A method of delivering a therapeutic dose of a bioactive agent to the pulmonary system, in a single, breath-activated step, comprising:  
administering particles, from a receptacle having a mass of particles, to a subject's respiratory tract,  
wherein the particles administered to the subject's respiratory tract have a tap density of less than  $0.4 \text{ g/cm}^3$  and deliver at least about 50% of the mass of particles.
  - 10 2. The method of Claim 1 wherein the particles have a tap density of less than about  $0.1 \text{ g/cm}^3$ .
  3. The method of Claim 1 wherein the particles have a geometric diameter greater than about  $5 \text{ }\mu\text{m}$ .
  4. The method of Claim 1 wherein the receptacle has a volume of at least about  
15  $0.37 \text{ cm}^3$ .
  - Sub 115
  5. The method of Claim 1 wherein the single receptacle has a volume of at least about  $0.48 \text{ cm}^3$ .
  6. The method of Claim 1 wherein the single receptacle has a volume of at least about  $0.67 \text{ cm}^3$ .
  - 20 7. The method of Claim 1 wherein the single receptacle has a volume of at least

*Sub a1st  
cont.*about ~~0.96~~ cm<sup>3</sup>.

8. The method of Claim 1 wherein delivery is primarily to the deep lung.
9. The method of Claim 1 wherein delivery is primarily to the central airways.
10. The method of Claim 1 wherein the bioactive agent is albuterol sulfate.
- 5 11. The method of Claim 1 wherein the bioactive agent is insulin.
12. The method of Claim 1 wherein the bioactive agent is growth hormone.
13. The method of Claim 1 wherein the bioactive agent is fluticasone.
14. The method of claim 1 wherein the bioactive agent is salmeterol.
15. The method of Claim 1 wherein the bioactive agent is a hydrophobic drug.
- 10 16. The method of Claim 1 wherein the bioactive agent is a hydrophilic drug.
17. The method of Claim 1 wherein the bioactive agent is a monoclonal antibody.
18. The method of Claim 1 wherein the particles are in the form of a dry powder.
19. The method of Claim 1 wherein administration to the respiratory tract is by a dry powder inhaler.

*Sub a1d*

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*a1b*

A method of delivering a therapeutic dose of a bioactive agent to the pulmonary

system, in a single breath, comprising:

administering particles, from a receptacle having a mass of particles, to a subject's respiratory tract,

wherein the particles have a tap density less than about  $0.4 \text{ g/cm}^3$  and deliver at least about 10 milligrams of the bioactive agent.

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21. The method of Claim 20 wherein the particles have a tap density of less than about  $0.1 \text{ g/cm}^3$ .

22. The method of Claim 20 wherein the particles have a geometric diameter greater than about  $5 \text{ }\mu\text{m}$ .

10 23. The method of Claim 20 wherein the receptacle has a volume of at least about  $0.37 \text{ cm}^3$ .

24. The method of Claim 20 wherein the single receptacle has a volume of at least about  $0.48 \text{ cm}^3$ .

15 25. The method of Claim 20 wherein the single receptacle has a volume of at least about  $0.67 \text{ cm}^3$ .

26. The method of Claim 20 wherein the single receptacle has a volume of at least about  $0.95 \text{ cm}^3$ .

27. The method of Claim 20 wherein the particles deliver at least 15 milligrams of the bioactive agent.

20 28. The method of Claim 20 wherein the particles deliver at least 20 milligrams of

sub-arg  
cont

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sub arg  
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the bioactive agent.

29. The method of Claim 20 wherein the particles deliver at least 30 milligrams of the bioactive agent.
30. The method of Claim 20 wherein the particles deliver at least 35 milligrams of the bioactive agent.
31. The method of Claim 20 wherein the particles deliver at least 50 milligrams of the bioactive agent.
32. The method of Claim 20 wherein delivery is primarily to the deep lung.
33. The method of Claim 20 wherein delivery is primarily to the central airways.
34. The method of Claim 20 wherein the bioactive agent is albuterol sulfate.
35. The method of Claim 20 wherein the bioactive agent is insulin.
36. The method of Claim 20 wherein the bioactive agent is growth hormone.
37. The method of Claim 20 wherein the bioactive agent is ipratropium bromide.
38. The method of Claim 20 wherein the bioactive agent is fluticasone.
39. The method of claim 20 wherein the bioactive agent is salmeterol.
40. The method of Claim 20 wherein the bioactive agent is a hydrophobic drug.

41. The method of Claim 20 wherein the bioactive agent is a hydrophilic drug.
42. The method of Claim 20 wherein the bioactive agent is a monoclonal antibody.
43. The method of Claim 20 wherein the particles are in the form of a dry powder.
44. The method of Claim 20 wherein administration to the respiratory tract is by a  
5 dry powder inhaler.

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